

U.S.S.N. 09/981,845

Filed: October 18, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION**Remarks**

Claims 1-6 are pending. Claims 1 and 2 have been amended. Claims 7-18 have been canceled. Support for the amendment to claim 2 can be found, for example, at page 4, lines 7-14; page 54; and Table 8.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-6 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The claims are directed to a peptide composition comprising SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, or SEQ ID NO:15. Claim 1 is not directed to regulating cellular development. Claim 2 is directed to a peptide which can be used to increase cell attachment to a biomaterial, and cell spread. The specification clearly teaches methods and techniques used to measure cell attachment and cell spread. For example, Example 12 of the originally filed application, illustrates the relative ease in which one of ordinary skill in the art may identify peptides exhibiting the claimed activities (for example, see claim 2). Plates are coated with any of osteopontin, SEQ ID NO:15, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, or SEQ ID NO:14. The plates are then treated with osteoprogenitor cells, the cells undergo a transformation from a neutral (uncoated condition) to a proactive condition in which the number of attached cells, as well as the percent spread, significantly increases (see

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Table 8). Table 8 also illustrates 1) antibodies to different integrins may be used to block binding to specific integrins; and 2) each of SEQ ID NO:15, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, or SEQ ID NO:14 bind to osteoprogenitor cells and significantly increase cellular attachment over the control. It should be noted that peptide size is not critical to binding since the peptide is able to bind when present in the intact full length peptide.

The applicants respectfully submit that one of ordinary skill in the art would be able to readily ascertain the functional binding activity of integrins and their cognate binding partners based upon the assays taught in the present specification. The applicants respectfully submit that the guidance and ease in carrying out the specification's described assays, as shown in the examples, would clearly enable one to treat coated plates with other types of cells expressing different types of receptor/integrin molecules, and assay for cell attachment and/or cell spread. As described throughout the specification, cell attachment and spread can additionally be measured by the change in cell volume to surface area, as well as the formation of stress fibers. Changes in morphological characteristics such as these, indicate that the cell is undergoing significant genetic and biochemical changes and being directed down a developmental pathway toward, for example, a differentiated phenotype (see, for example, page 54, lines 2-10). The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides

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a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 2 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 2 is directed to a peptide increasing the contact between cells and a biomaterial. The applicants respectfully submit that the term "increasing attachment and cell spread" is definite, since it is relative to attachment between the cells and biomaterial in the absence of the peptide.

Rejection Under 35 U.S.C. § 102

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Young *et al.* Genomics, (Abstract) 7(4):491-502, 1990 by ("Young"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The claimed peptide compositions do not include human osteopontin.

Claim Objections

Claims 1 and 6 were objected to as being drawn to a non-elected invention. Applicants understand that, although they were required to select single species from each of the claims listed in the office action mailed on March 6, 2003, the examiner will examine the other species once the initially elected species is determined to be allowable for each of the claims.

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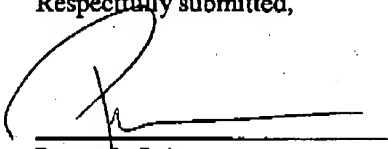
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Claim 6 is proper. Claim 6 narrows the scope of claim 3 by restricting the cell types to specific cells.

Allowance of claims 1-6 is respectfully solicited.

Respectfully submitted,



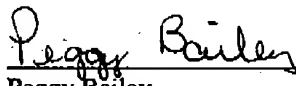
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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, **November 21, 2003**, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



Peggy Bailey

Date: November 21, 2003

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